

## **REMARKS**

### **Support for Amendments to Claims**

Claims 1 through 12 have been amended to replace the phrase “peptide conjugate” with the term “lipopeptide detergent”, in order to more distinctly define the claimed subject matter of the application. This amendment is supported by the description, as the term “lipopeptide detergent” is used throughout.

Claim 1 has been further amended to more clearly define the peptide moiety of the claimed lipopeptide detergent by indicating that this peptide moiety has an amino acid sequence selected so as to permit the formation of the peptide moiety into an amphipathic  $\alpha$ -helical conformation. This amendment is supported by the description on pages 8 and 9. As well, claim 1 has been amended to additionally clarify that the aliphatic moieties of the lipopeptide detergent are linked such that they associate with a hydrophobic region of the peptide moiety of the claimed lipopeptide detergent. Support for this amendment is found on page 8, where reference is made to the hydrophobic face of the peptide, and on page 13 (lines 12 to 14), where it is indicated that the aliphatic hydrocarbon moieties are linked in a covalent manner to both the N- and C- termini of the peptide or to sites near each of these termini such that they associate with the hydrophobic region of the peptide.

New claim 13 has been added to the application to specifically claim the lipopeptide detergent as defined in the main claim, wherein the aliphatic hydrocarbon moieties comprise from about 8-24 carbon atoms, and the peptide has the amino acid sequence AOAEEAAEKAAKYAAEAAEKAAKAOA. Support for this new claim is found in Example 1 on page 16, line 22, to page 17, line 3, where the length of the aliphatic hydrocarbon moiety is described in specific terms relative to the defined amino acid sequence, respectively. Examples 2 and

3 of the description also refer to certain lipopeptide detergents as claimed in new claim 13.

New Claim 14 has been added to the specification to specifically claim a lipopeptide detergent as defined in claim 1, wherein the N-terminus of said peptide is acetylated and the C-terminus of said peptide is amidated, the peptide has the amino acid sequence AOAEAAEKAAKYAAEAAEKAAKAOA, and each of the aliphatic hydrocarbon moieties comprises 12 carbons atoms. Support for this new claim is found in Examples 1 to 3 of the description.

New claim 15 has been added to the specification to specifically claim a lipopeptide detergent as defined in new claim 14, wherein the aliphatic hydrocarbon moieties are covalently linked to said peptide moiety via the ornithine residues of the amino acid sequence. This claimed subject matter is supported by Example 1 of the description, where the synthesis of the lipopeptide detergents is described.

New claim 16 has been added to specifically claim a composition comprising membrane proteins stabilized by the use of lipopeptide detergents as defined in claim 1. The description supports the use of the lipopeptide detergents of the invention for this purpose on page 1 (lines 7 to 9), page 14 (lines 2 to 11) and Figure 1D, and in Example 2 and accompanying Figures 2A-D.

New claim 17 has been added to specifically claim a composition comprising biological membranes modified by the use of lipopeptide detergents as defined in claim 1. Support for the addition of new claim 17 is found in the description on page 1 (lines 9 to 12), page 14 (line 22) to page 15 (line 2), and in Example 3 and accompanying Figure 3.

### **Election/Restrictions**

The Office Action acknowledges the applicant's previously submitted election of species and now seeks to require the applicant to submit claims limited in scope to the elected species, which was a conjugate of the peptide of SEQ ID NO: 1 and the detergent species LPD-16. However, there is no requirement in the law

for the applicant to limit his claims to individual species. On the contrary, it is clearly permissible for an applicant to present generic claims, without any species claims. See M.P.E.P. Section 809.02(d). Applicant therefore requests examination of his amended generic claims on the merits in accordance with the provisions of the M.P.E.P.

**Claim Rejections – 35 USC § 112 1<sup>st</sup> paragraph**

Claims 1-12 were rejected for lack of enablement, stating that the specification, while being enabling for the peptide of SEQ ID NO: 1 in the invention's "peptide conjugate", does not reasonably provide enablement for any other peptides in the "peptide conjugate". Applicant acknowledges that the specification only provides specific Examples with reference to the peptide of SEQ ID NO: 1 in the lipopeptide detergent. However, Applicant respectfully submits that there is sufficient teaching in the description and in the art such that one skilled in the art would be capable of working within the invention as claimed, for the following reasons.

Claim 1 has been amended, such that the claim is no longer drawn broadly to a "peptide conjugate". Applicant submits that the amendments to claim 1 more clearly define the nature of the invention, and the invention is now drawn to "A lipopeptide detergent, wherein the peptide moiety of said lipopeptide detergent has an amino acid sequence selected so as to permit the formation of the peptide moiety into an amphipathic  $\alpha$ -helical conformation...". The amendments to claim 1 are in keeping with the teaching of the description on pages 8 and 9.

As noted in the Office Action, the description on page 8 teaches that the peptide scaffold or moiety of the lipopeptide detergent is not particularly limited with respect to its amino acid sequence, and that the amino acid sequence is selected so as to permit formation of the peptide scaffold or moiety into an amphipathic  $\alpha$ -helical conformation. Applicant respectfully submits that further details as well as literature references are provided on page 8 regarding the amino acids that may be included in the hydrophobic and hydrophilic regions of the peptide, in

order to promote the formation of the peptide scaffold or moiety into an amphipathic  $\alpha$ -helical conformation. As well, on page 9 of the specification, the selection of terminal amino acids to promote  $\alpha$ -helix formation is also described. Applicant therefore submits that there is sufficient teaching in the description and in the art so as to enable a person skilled in the art to determine which peptides will form an amphipathic  $\alpha$ -helical conformation.

The Office Action also states that it is not clear as to what amino acids may be included (referring to common, uncommon, and non-peptide amino acids) and the ultimate peptide structure, with the substantial variability among what amino acids may be encompassed by the broad claim language of former claim 1. Applicant submits that amended claim 1 more distinctly defines the invention, and the broad claim language having regard to the "peptide conjugate" of former claim 1 has been removed. Applicant further submits that as there is sufficient teaching in the description (on pages 8 and 9) and in the art to enable one of skill in the art to determine which peptides would form an  $\alpha$ -helical conformation, and as claim 1 has been amended to distinctly claim "A lipopeptide detergent, wherein the peptide moiety of said lipopeptide detergent has an amino acid sequence selected so as to permit the formation of the peptide moiety into an amphipathic  $\alpha$ -helical conformation...", Applicant respectfully submits that the Examiner's objection to the claims on the basis of lack of enablement should be withdrawn.

**Claim Rejection – 35 USC § 112 2<sup>nd</sup> paragraph**


Claims 1-12 were rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant submits that amended claim 1, as previously stated, more distinctly defines the invention as "A lipopeptide detergent, wherein the peptide moiety of said lipopeptide detergent has an amino acid sequence selected so as to permit the formation of the peptide moiety into an amphipathic  $\alpha$ -helical conformation...". Original Claim 4 has also been amended to claim the

lipopeptide detergent as defined in claim 1, wherein the peptide comprises 15-35 amino acids. The Office Action asserts that it is unclear what the invention is, regarding the structure of the "peptide conjugate", since the structure/sequence of the peptide(s) is/are unclear. Applicant submits that as claim 1 has been amended to more distinctly claim a lipopeptide detergent wherein the peptide moiety of the lipopeptide detergent has an amino acid sequence selected so as to permit the formation of the peptide moiety into an amphipathic  $\alpha$ -helical conformation, and as one skilled in the art would be sufficiently enabled to determine which peptides would form an  $\alpha$ -helical conformation based on the teaching of the description and the state of the art, that the invention has been clearly defined in terms of the structure/sequence of the peptide. Therefore, Applicant submits that the rejection of the claims on the basis of indefiniteness should be withdrawn.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned at (202) 624-2845 would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #01078247985).

Respectfully submitted,

  
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October 28, 2004  
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